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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,794	07/02/2003	Guy Vanney	0B-044900US-82410.0195	7352

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SJM/AFD-WILEY
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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,794	VANNEY, GUY	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 5, 2009 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 3-6, 10, 11, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,001,093) in view of the teaching of Burns et al (3,773,034).

As shown in Figures 40-45, Swanson et al disclose an ablation device comprising a tubular body (200) having a circumference and a distal end region, the tubular body having a partial curve that is adapted to change (see Figure 40). At least one ablating electrode (202) is provided along the curve and changes curve along with the tubular body (Figure 40). The electrode is configured to be flexible and to extend around only a portion of the circumference of the tubular body (see cross-sections of Figures 41A/B, 42A/B and 45). Figure 45 is deemed to read on a "saw-tooth" pattern given the peaks and valleys created by the electrode, and the electrode extend along

the radius of the curve as shown in Figure 40. Regarding claims 10 and 11, Swanson et al do not specifically show a closed loop or open loop structure associated with the embodiment of Figures 40-45. However, earlier embodiments (Figure 27) clearly show that Swanson et al intended to create a wide range of shapes including open and closed loops. The examiner maintains that making any desired loop shape with the embodiment shown in Figures 40-45 would have been an obvious design consideration for the skilled artisan, particularly since Swanson et al clearly teach that such shapes are contemplated. While Swanson et al disclose a means to bend the catheter, there is no specific disclosure of an actuating lumen sealed at the distal end and used to provide fluid pressure to the lumen to cause bending of the catheter body.

Burns et al teach that it is generally known to use a fluid lumen, or a plurality of fluid lumens, having a closed distal end such that a fluid pressure may be provided in the lumen(s) to cause the catheter to bend. See Abstract and column 2.

To have provided the Swanson et al catheter with an actuation lumen to control bending of the catheter via fluid pressure would have been an obvious design modification for one of ordinary skill in the art, particularly since Burns et al teach it is known to use such an actuation lumen to control catheter bending.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('093) and Burns et al ('034) as applied to claim 1 above, and further in view of Maschino et al (US 6600956 B2).

Swanson et al and Burns et al discloses the ablation catheter of claim 1 wherein the electrode is biasedly coupled with the at least partial curve along the distal end region of the tubular body (Figure 40), and wherein the biased connection is biased to change the curvature of the at least partial curve along the distal end region of the tubular body. Swanson et al do not disclose an elastically deformable electrode. Maschino teaches that it is known in the medical art to form electrodes so they are elastically deformable (column 4 lines 11-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Swanson et al, as modified by the teaching of Burns et al, by making the electrodes elastically deformable so that the electrode can stretch under small stresses in order to facilitate the curving of the tubular member.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('093) and Burns et al ('034) as applied to claim 1 above, and further in view of Kordis (5,499,981).

Swanson et al fail to disclose an interlaced electrode as set forth in these claims. Kordis discloses another ablation catheter that includes a tubular body (98) having electrodes (92) extending along a curved length of the tubular body. The electrodes are strands that are interlaced along the length of the tubular member to create an intermittently exposed series of electrodes. It is noted that Swanson et al also disclose the use of intermittent electrodes to create different lesion patterns.

To have provided the Swanson et al device, as modified by the teaching of Burns et al, with an interlaced series of electrodes to provide a flexible pattern of electrodes extending along a flexible tubular body would have been an obvious design choice for one of ordinary skill in the art in view of the teaching of Kordis.

Claims 1, 3-6, 10, 11, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,171,306) in view of the teachings of Swanson et al (6,001,093) and Burns et al ('034).

Regarding claim 1, Swanson ('306) discloses an ablation catheter (12) comprising: a tubular body (flexible body, 42, Fig 6) having a distal end region, the tubular body defining at least a partial curve along the distal end region of the tubular body (see Fig 6), the partial curve being adapted to change curvature (via steering mechanism 18, column 7 lines 31-35); and at least one electrode (44) arranged along the at least partial curve (Fig 6), the at least one ablating electrode being adapted to change curvature along with the at least partial curve along the distal end region of the tubular body (column 7 lines 54-57 and column 8 lines 7-11), wherein the at least one electrode is configured to be flexible and resilient (column 7 lines 26-57). Swanson ('306) fails to disclose an electrode that extends around only a portion of the circumference of the tubular body and also fails to disclose an actuation lumen that uses fluid pressure to steer the catheter body.

Swanson et al ('093) disclose substantially the same system, and further teach that it is known to provide an electrode on only a portion of the circumference of the

tubular body, the electrode being provided on the flexible portion of the catheter. Specifically, Figures 40-42 show an embodiment with one or more electrodes (202) disposed along a curved length of the catheter, the electrode being formed around only a portion of the circumference of the catheter body (see cross sectional views). Figures 43 and 45 disclose alternative embodiments of electrodes extending around only a portion of the circumference of a catheter in the curved region.

As addressed above, Burns et al further teach that it is known to use an actuating lumen having a sealed distal end such that fluid pressure may be used to control the bending of the catheter body.

To have provided the Swanson ('306) electrode as a series of longitudinally extending electrodes as taught by Swanson et al ('093) is deemed an obvious design modification, particularly since Swanson et al ('093) discloses a substantially identical device for the same purpose. To have further provided the Swanson ('306) catheter with an actuation lumen to provide a fluid pressure to cause bending of the catheter body would have been an obvious alternative steering mechanism since Burns et al fairly teach it is known to use such an actuation lumen to control the bending of catheters.

Regarding claim 3, Swanson discloses the ablation catheter of claim 1 further comprising a flexible and resilient shaping element (26).

Regarding claim 4, Swanson discloses the ablation catheter of claim 1 wherein the at least one flexible and resilient electrode is comprised, at least partially, of material

selected from the group consisting of platinum, gold, stainless steel, and composite of conductive polymer metal (column 7 lines 38-40).

Regarding claim 5, Swanson discloses the ablation catheter of claim 1 wherein the at least one electrode strand defines a saw tooth pattern (formed by the cylindrical wire being wound around the tubular body; see Figs 6, 7A and 9).

Regarding claim 6, Swanson discloses the ablation catheter of claim 1 wherein the at least partial curve defines an outside radius (inherent with a curved tube), and wherein the at least one electrode defines a first end region and a second end region, and wherein the first end region is coupled with a point along the outside radius of the at least partial curve and wherein the second end region is coupled with a second point along the outside radius of the at least partial curve along the distal end region of the tubular body (see Figs 6 and 10).

Regarding claim 10, Swanson discloses the ablation catheter of claim 1 wherein the at least partial curve along the distal end region of the tubular body defines a closed loop (Fig 17B).

Regarding claim 11, Swanson discloses the ablation catheter of claim 1 wherein the at least partial curve along the distal end region of the tubular body defines an open loop (Fig 17A).

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson ('306), Swanson ('093) and Burns et al ('034) as applied to claim 1 above, and further in view of Maschino et al (US 6600956 B2).

Swanson discloses the ablation catheter of claim 1 wherein the electrode is biasedly coupled with the at least partial curve along the distal end region of the tubular body (Figs 6 and 7A-8B), and wherein the biased connection is biased to change the curvature of the at least partial curve along the distal end region of the tubular body (Fig 6). Swanson does not disclose an elastically deformable electrode. Maschino teaches that it is known in the medical art to form electrodes so they are elastically deformable (column 4 lines 11-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Swanson('306), as modified by the teachings of Swanson ('093) and Burns ('034), by making the electrodes elastically deformable so that the electrode can stretch under small stresses in order to facilitate the curving of the tubular member.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson ('306), Swanson et al ('093) and Burns et al ('034) as applied to claim 1 above, and further in view of Kordis (5,499,981).

Swanson ('306) and Swanson et al fail to disclose an interlaced electrode as set forth in these claims. Kordis discloses another ablation catheter that includes a tubular body (98) having electrodes (92) extending along a curved length of the tubular body. The electrodes are strands that are interlaced along the length of the tubular member to create An intermittently exposed series of electrodes. It is noted that Swanson et al also disclose the use of intermittent electrodes to create different lesion patterns.

To have provided the Swanson ('306) device, as modified by the teaching of Swanson et al ('093) and Burns et al ('034), with an interlaced series of electrodes to provide a flexible pattern of electrodes extending along a flexible tubular body would have been an obvious design choice for one of ordinary skill in the art in view of the teaching of Kordis.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. The examiner has provided new prior art to address the newly recited limitations.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boretos (4,403,985) and Sinofsky (5,123,421) disclose alternative devices using fluid lumens and fluid pressure to control catheter deflection. Vanney (7,101,362) disclose substantially the same device as addressed in the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
June 4, 2009